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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,355	09/26/2006	Keith Alan Charlton	133088.01101(P38578US)	7281

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,355	CHARLTON ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4,5,7-9,17,18 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,10-16,19 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *multiple*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed October 21, 2009 has been received and entered. Claims 27-40 have been cancelled. Accordingly, claims 1-26 remain pending in the instant application, of which claims 4-5, 7-9, 17-18, and 20-22 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 13 and 26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants are asserting that pages 32-39 of the specification set forth that the microorganisms were all deposited with NCIMB Ltd. Of Scotland, and that an accompanying "Budapest Treaty On The International Recognition Of The Deposit Of Microorganisms For The Purposes Of Patent Procedure" for each of the deposits have been executed by a person having power to represent the International Depository Authority. Applicants conclude that this documentation is sufficient.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, the strains have been deposited under the Budapest Treaty as asserted above, and the accompanying "Budapest Treaty On The International Recognition Of The Deposit Of Microorganisms For The Purposes Of Patent Procedure" for each of the

deposits have been executed by a person having power to represent the International Depository Authority have been received. However, Applicants conclusion that this documentation is sufficient is simply incorrect. Applicants attention is drawn to the following requirements (highlighted in bold this time) which must be satisfied above and beyond what Applicants have to this point submitted:

The specification lacks complete deposit information for the deposit of NCIMB-41167, NCIMB-41168, NCIMB-41169 and NCIMB-41170 it is not clear that host cells possessing the identical properties of NCIMB-41167, NCIMB-41168, NCIMB-41169 and NCIMB-41170 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a host cell is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed cell, this method will not necessarily reproduce host cells which are chemically and structurally identical to those claimed. Undue experimentation would be required to screen all of the possible species to obtain the claimed host cells.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the NCIMB-41167, NCIMB-41168, NCIMB-41169 and NCIMB-41170 host cells a suitable deposit for patent purposes, evidence of public availability of the NCIMB-41167, NCIMB-41168, NCIMB-41169 and NCIMB-41170 host cells or evidence of the reproducibility without undue experimentation is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that ***all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty***

leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1 and 14 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "lactone derived signal molecule" is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 1-3, 6, 10-16, 19, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton et al is maintained.

Applicants are asserting that although the Charlton reference reports treatment of an "infection" it does not describe or even suggest that administration of the antibodies would cause autolysis in a population of bacteria. Applicants further assert that it is

well established in the art that the treatment of bacterial infection can encompass the use of bacteriostatic or bactericidal compositions (or combinations thereof). Applicants conclude that evidence suggesting the bacteriostatic effect of a composition in no-way suggests that a composition consisting of the same components would have a bacteriocidial effect on a population of bacteria.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that although the Charlton reference reports treatment of an "infection" it does not describe or even suggest that administration of the antibodies would cause autolysis in a population of bacteria. However, Applicants are respectfully reminded that Charlton discloses the identical monoclonal antibodies elicted against the identical structure (Formula I) as instantly claimed (NCIMB-41167, 41168, 41169 & 41170; see page 17). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show

inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999).

Finally, Applicants assert that it is well established in the art that the treatment of bacterial infection can encompass the use of bacteriostatic or bactericidal compositions and that evidence suggesting the bacteriostatic effect of a composition in no-way suggests that a composition consisting of the same components would have a bacteriocidial effect on a population of bacteria. Applicants arguments are in general correct, however Applicants have not addressed how the identical antibody (NCIMB-41167, 41168, 41169 & 41170) could possiblly be bacteriostatic in one composition or bacteriocidial in another composition. Indeed, given that they are the identical antibodies they will inherently have the identical property of being bactericidal.

The claims are directed to a method of causing autolysis of a population of gram-negative bacteria in need of inducing a collapse in bacterial cell numbers, said method comprising administration to the population of an antibody to a lactone or lactone-derived signal molecule secreted by gram-negative bacteria so as to cause an imbalance in the ration of homoserine lactone (HL) signal molecule to quinolone signal (QS) signal molecule in the environment of the population of the gram-negative

bacteria.

Charlton et al (WO 2004/014423) disclose of methods for the treatment of an infectious bacterial disease with an anti-lactone signal molecule antibody. (See Title and abstract). Charlton et al further disclose of the Homoserine lactone of Formula I (See page 13, Formula I).

It is noted that Charlton et al do not characterize the antibody as "causing an imbalance in the ration of homoserine lactone signal molecule to quinolone signal molecule." However, given that the monoclonal antibody disclosed by Charlton et al is elicited against the identical structure (Formula I) it is deemed to be an inherent property of the elicited antibody. This is further a necessary result as Charlton et al disclose of the identical antibodies (NCIMB-41167, 41168, 41169 & 41170) as claimed. (See page 17).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163

USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. The rejection of claims 1-3, 6, 10-16, 19, and 23-26 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/524,082 is withdrawn in view of the amendment to the claims in '082.

5. The rejection of claims 1-3, 6, 10-16, 19, and 23-26 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 11/568,673 is maintained.

Applicants are asserting that there is no explanation why the claims of the present application (i.e., method of screening a naïve human phage display library for an anti-bacteria in a subject) are obvious variants of for example, claim 1 of 11/568,673, which recites a method of preventing or inhibiting biofilm formation by a population of bacteria.

Applicants arguments have been fully considered but are not found to be persuasive.

It appears Applicants have looked at the wrong claim set for the instantly filed claims. The claims are in fact drawn to "A method of causing autolysis of a population

of gram-negative bacteria…" not "screening a naïve human phage display library" as asserted. The method of causing autolysis in the instantly filed claims is an obvious variant of the claims of '673, drawn to preventing biofilm, given that both methods require administration of the identical antibody for the purpose of eradicating bacteria.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of administering antibodies immunoreactive with Formula I homoserine lactone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
January 13, 2010